

DILCEREN[®] TABLET

Consumer Medication Information Leaflet (RiMUP)

Nimodipine 30mg

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What Dilceren is used for

Dilceren is in a group of drugs called calcium channel blockers. Dilceren relaxes (widens) blood vessels and improves blood flow. It is used to prevent brain damage caused by reduced blood flow to the brain resulting from a dilated or ruptured blood vessel in the brain.

How Dilceren works

Dilceren is a lipophilic dihydropyridine calcium-channel blocker acting primarily on receptor-dependent calcium channels, with a predilective anti-vasoconstrictive and anti-ischaemic effect on cerebral blood vessel. In patient with subarachnoid haemorrhage, nimodipine prevents arterial spasm, dilates cerebral blood vessels and enhances cerebral blood flow. In particular, it normalizes blood flow in regions of vascular spasms, thus improving cerebral perfusion. Dilceren does not accumulate in the body with repeated administration of therapeutic doses.

Before you use Dilceren

When you must not use it

Dilceren should not be used in individuals with known hypersensitivity to nimodipine or other ingredients in the preparation.

Pregnancy and lactation

Dilceren must not be used during pregnancy and lactation.

Use in Children

Dilceren should not be administered to children and adolescents below 18 years of age.

Before you start use it

Make sure your doctor or pharmacist knows if you are:

- Pregnant or breast-feeding
- Have kidney and liver problems
- If you have porphyria (a rare blood disorder)
- Have low blood pressure
- If you have cerebral oedema (brain swelling)
- Severely raised intracranial pressure (pressure inside skull phenomena)

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Do not combine Dilcerin with antihypertensive agents, diuretics or beta-blocker medicines as it can lead to hypotension and cardiac failure.

Avoid taking antiepileptic drug, phenobarbital or carbamazepine together with Dilcerin as it may cause significant reduction of plasma levels of Dilceren.

The intake of cimetidine and the anti-convulsant valproic acid and grapefruit juice result in an increase in the plasma levels of Dilceren. Do not take these medications together Dilceren.

How to use Dilceren

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommend procedure before start taking Dilceren tablet is to administered nimodipine infusion for 5-14 days, followed by a daily dose of 60mg Dilcerin tablet every 4 hrs (or 6 times).

When to use it

Use as directed by your doctor or pharmacist.

Tablets should be swallowed whole with a little fluid, irrespective of meal-times.

The interval between consecutive doses should not be shorter than 4 hours.

How long to use it

Continue taking Dilceren for as long as your doctor recommends.

If you forget to use it

Take your normal dose immediately and carry on taking that day's tablets at 4-hour intervals. Do not take a double dose to make up the missed tablet.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Acute overdose may present with symptoms such as facial flushing, headache, hypotension, tachycardia or bradycardia, gastrointestinal complaints and nausea.

In event of acute overdosage, Dilceren must be discontinued immediately. There is no specific antidote and symptomatic management should be instituted. If nimodipine has been ingested orally, gastric lavage and administration of oral activated charcoal should be considered as an emergency measure. If marked hypotension occurs, intravenous dopamine or noradrenaline should be administered. Hemodialysis is not effective.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Dilceren.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

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Do not drink grapefruit juice or eat grapefruit while taking Dilceren tablets. Grapefruit juice is known to increase blood levels of active ingredient, nimodipine.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Dilceren to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

The side-effects include:

- marked hypotension
- tachycardia
- dizziness
- weakness
- headache
- facial flushing
- feeling of warmth
- gastrointestinal complaints
- nausea
- peripheral oedema

Some patients may experience:

- insomnia
- restlessness
- irritability
- aggressiveness
- sweating

In very rare cases:

- hyperkinesia
- Depressive mood
- Thrombocytopenia
- Intestinal ileus
- Signs of heart failure

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you

think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Dilceren

Storage

- Keep out of the reach of children.
- Store below 25 °C.
- Protect from light.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

White biconvex coated tablet.

Ingredients

Active ingredient

Nimodipine

Inactive ingredients

Cellulose microcrystalline

Corn starch

Polyvidone insoluble

Polyvidone K 25

Calcium stearate

Hypromellose

Macrogol 6000

Dichloromethane

Titanium dioxide

Talcum

Purified water

MAL number:

MAL20021138A

Manufacturer

Slovakofarma, Zelznica 12, 92027 Hlohovec, Slovak Republic.

Product Registration Holder

Pahang Pharmacy Sdn Bhd

Lot 5979, Jalan Teratai, 5 ½ Miles, Off Jalan Meru, 41050 Klang, Selangor

Date of revision

26/11/2013